

OMET 201 US (10104949)REMARKS

In light of the above amendments and remarks to follow, reconsideration and allowance of this application are requested.

New claims 41-45 have been added, claims 7, 11, 16, 24 and 28 have been cancelled, and claims 1, 10, 14, 17, 18, 27, 34-35, and 39-40 have been amended herein. Support for the recitation in claim 41 is set forth on page 33, lines 13-22, and page 47, lines 22-24. Support for recitation in claims 42-45 is set forth on pages 35, line 3 through page 40, line 12. Accordingly, claims 1-6, 8-10, 12-15, 17-23, 25-27, and 29-45 are presented for consideration.

Claims 1-7, 9-11, 13-24, 26-28, and 31-40 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Ware et al. (The Search for More Practical and More Precise Outcomes Measures, The Quality of Life Newsletter, January 1999-April 1999). Moreover, claims 8, 12, 25, and 29 have been rejected under 35 U.S.C. 103(a) as being allegedly unpatentable over Ware et al. Applicants respectfully traverse these rejections.

Ware et al. describes a fixed test that begins with an initial estimate of the respondent's score, which is calculated based on population average, and the selection of a "most informative item." (Ware et al., page 12, column 1). However, Ware et al. does not describe (1) the generation of a customizable test based on the patient's characteristics, and one or more domains; nor (2) the selection of one or more health domains to be assessed by the patient whose health status or care is being assessed, or by a health care provider, as required by amended independent claims 1, 18, 35, 39. Accordingly, amended claims 1, 18, 35, and 39 are patentably distinct over Ware et al.

Further, Ware et al. describes a question being selected based on the estimated score. (Ware et al., page 12, column 1-2). However, contrary to the Examiner's assertions, Ware et al. does not describe a threshold which varies as a function of the estimated score, as required by the amended claims 1, 18, 35, and 39 (originally recited in cancelled claims 7 and 24). Specifically, Ware et al., page 12, column 1-2, only describes a fixed preset standard of precision based on the confidence interval. Accordingly, amended claims 1, 18, 35, and 39 are patentably distinct over Ware et al.

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Of course, a rejection based on 35 U.S.C. §102 requires that the cited reference disclose each and every element covered by the claim. Electro Medical Systems S.A. v. Cooper Life Sciences Inc., 32 U.S.P.Q.2d 1017, 1019 (Fed. Cir. 1994); Lewmar Marine Inc. v. Barient Inc., 3 U.S.P.Q.2d 1766, 1767-68 Fed. Cir. 1987), cert. denied, 484 U.S. 1007 (1988); Verdegaal Bros., Inc. v. Union Oil Co., 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir.), cert. denied, 484 U.S. 827 (1987). The Federal Circuit has mandated that 35 U.S.C. §102 requires no less than "complete anticipation . . . [a]nticipation requires the presence in a single prior art disclosure of all elements of a claimed invention arranged as in the claim." Connell v. Sears, Roebuck & Co., 772 F. 2d 1542, 1548, 220 U.S.P.Q. 193, 198 (Fed. Cir. 1983); see also, Electro Medical Systems, 32 U.S.P.Q. 2d at 1019; Verdegaal Bros., 814 F.2d at 631.

Moreover, to establish a prima facie case of obviousness, three basic criteria must be met. First there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991); MPEP 2143. Here, the Examiner has failed to establish a prima facie case of obviousness because Ware et al. does not teach or suggest all the claim limitations of amended claims 1 and 18 and thus also included in dependent claims 8, 12, 25, and 29.

In view of the foregoing differences and authorities, it is respectfully submitted that Ware et al. does not anticipate or render obvious claims 1, 18, 35, and 39, or any of claims 2-17, 19-34, 36-38, and 40 dependent on claims 1, 18, 35, and 39, respectfully.

New claim 41 depends from claim 1, and additionally recites the limitation that at least two health domains are selected and assessed. New claims 42-45 depend from claim 1, 18, 35, and 39, respectfully. Each of these new claims additionally recite the limitation that the test is administered before and after a particular variable is introduced, and then resultant data obtained from each separate administration of the test is compared. The resultant data is indicative of the efficacy or impact of the introduction of a particular variable on the health status or health care

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of a patient. The allowance of claims 41-45 are solicited for the reasons given above with respect to claims 1, 18, 35 and 39.

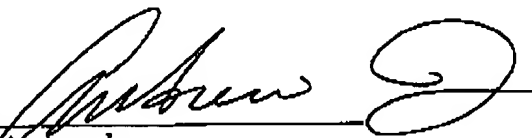
In view of the foregoing, withdrawal of all rejections and allowance of this application are respectfully requested.

Statements appearing above in respect to the disclosures in the cited references represent the present opinions of applicant's undersigned attorney and, in the event that the Examiner disagrees with any of such opinions, it is respectfully requested that the Examiner specifically indicate those portions of the reference providing the basis for a contrary view.

Applicant believes no fee is due. However, if a fee is due, please charge our Deposit Account No. 50-0624, under Order No. QMET 201 (10104949) from which the undersigned is authorized to draw.

Respectfully submitted,

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